A Pilot Randomized Controlled Trial of Flexion-Distraction Dosage for Chiropractic Treatment of Lumbar Spinal Stenosis

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Abstract

Objective: The purpose of this pilot clinical trial was to assess the feasibility of recruiting older adults with lumbar spinal stenosis (LSS) into a clinical trial that used different dosages of flexion-distraction manipulation.

Methods: This randomized controlled trial used a 4-group design. Three groups consisted of chiropractic flexion-distraction manipulation applied at different dosages (8, 12, or 18 treatments). The fourth group was given 8 treatments of placebo care. Feasibility measures included recruitment goals, adherence to various treatment schedules, credibility of the placebo treatment, and rates of adverse events. The primary outcome measure was the Swiss Spinal Stenosis Questionnaire, a validated self-report of LSS symptom severity and physical function.

Results: The recruitment and adherence goals of the study were met with a total of 60 subjects randomized (n = 15 per group) and most subjects attending at least 75% of their scheduled visits. No adverse events were reported by any of the subjects in the trial. Our placebo treatment did not appear to be credible; most subjects correctly guessed that they were receiving a placebo treatment. Between-group effect size estimates were small, indicating larger samples are needed for future studies.

Conclusion: This pilot study showed that it is feasible to recruit patients with LSS and that most subjects will adhere to a 6-week treatment schedule. The information gained from this trial will be useful to inform the design of larger trials. (J Manipulative Physiol Ther 2014;37:396-406)

Key Indexing Terms: *Spinal Stenosis; Manipulation, Chiropractic; Low Back Pain; Complementary Therapies; Lumbar Vertebrae*

Symptomatic lumbar spinal stenosis (LSS) is a clinical condition that is a composite of both arthritis and back pain, the 2 most common causes of disability in American adults.[1] Lumbar spinal stenosis has a reported point incidence of up to 10% of the US adult population,[2] accounting for 3.8% of all general medical visits and 13.1% of all medical visits to a specialist.[3] Radiographic and clinical data from the Framingham cross-sectional study reports the prevalence of degenerative LSS (anatomical) at 30% in older adults.[4]

Lumbar spinal stenosis is a degenerative arthritic disease of the spine, which is often associated with significant functional limitations of walking and disability.[5] Although LSS is not a life threatening, the associated functional limitations of physical activity can lead to decreased quality of life.[6] Substantial leg pain and walking intolerance are the hallmark symptoms of LSS, which often lead to a dramatic impairment in ambulation and increased risk of falling, comparable to patients with severe knee osteoarthritis.[7,8]

The treatment options for patients with LSS fall into 2 main categories: (1) surgical care and (2) nonsurgical care. Lumbar spinal stenosis is the most common diagnosis associated with lumbar spinal surgery in persons older than 65 years,[9] with the fastest growth in lumbar surgery in the United States occurring in older adults with LSS.[10] Yet, there is a difference of opinion as to the appropriateness of

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surgical vs nonsurgical care as the first course of treatment in LSS. An article by the American Academy of Family Physicians stated, "early surgery is the best way to return [a stenotic patient] to full activity and independent living."[11] The largest randomized trial and cohort study comparing nonsurgical and surgical treatments for LSS demonstrated that surgery led to a significant improvement in pain and function over 4 years.[12,13] However, other authors have questioned this conclusion, stating "because rapid symptomatic or functional decline is rare in patients with LSS, a course of nonsurgical management is recommended."[14] This discrepancy between recommendations for or against LSS surgery can be attributed to a lack of sufficient controlled clinical trials about the effectiveness and appropriateness of nonsurgical treatment options.

Flexion-distraction (F-D) is a method of segmental spinal mobilization using a specialized table that allows the clinician to introduce gentle manually assisted traction forces.[15]

The National Board of Chiropractic Examiners has conducted 4 national surveys of the chiropractic profession over the past 20 years (1991, 1998, 2003, and 2009)[16-19] to identify the most commonly used treatment procedures. More than 56% of chiropractors in the most recent survey responded that they routinely employed F-D in their practices, the fifth most commonly reported technique. The Mercy Center Consensus Conference to establish practice guidelines for chiropractic physicians rated the F-D treatment procedure as "established."[20]

The hypothesized mechanisms of action of F-D care appear to match the needs of patients with spinal stenosis. These mechanisms[21] are hypothesized to (1) increase the intervertebral disk height to remove annular distortion within the pain-sensitive peripheral portion of the intervertebral disk; (2) decrease intradiscal pressure by creating a centripetal force on the protruding nucleus pulposus allowing it to assume a more central position within the annulus fibrosus; (3) remove subluxation of the facet articulations and restore physiologic motion to the posterior elements of the vertebral motion segment; and (4) improve posture and locomotion while relieving pain, improve body function, and restoring a state of well-being.

Phase 1 clinical trials help to determine the most effective dose of a given treatment prior to any large scale study. In chiropractic and physical therapy practice, the dose or the amount of care a patient receives may vary based on pain severity and chronicity as well as other factors. Clinicians determine a treatment schedule based on their previous training and patient experience, yet this information is often anecdotal. This randomized clinical trial was designed as pilot feasibility study to explore the efficacy of 3 different amounts of F-D treatment dosage over 6 weeks.

This pilot study was designed to gather information on the following 5 issues: (1) feasibility of recruitment and randomization; (2) adherence rates to different treatment dosages/schedules; (3) credibility of our placebo "treatment"; (4) safety, that is, rates of adverse events; and (5) point estimates of treatment effect sizes for future power analyses.

Methods

A sample of 60 volunteer subjects with LSS was recruited for the current investigation. Subjects were evenly randomized into 4 groups of either F-D care or placebo care: (1) group 1 receiving a total of 8 total placebo visits, (2) group 2 receiving a total of 8 F-D treatments; (3) group 3 receiving a total of 12 total F-D treatment visits, or (4) group 4 receiving a total of 18 total F-D treatment visits. The institutional review board at the National University of Health Sciences approved the trial, and written informed consent was obtained from all patients before their entry into the study. This trial was registered on the ClinicalTrials.gov Web site (identifier: NCT00527527).

Telephone Screening

Each interested subject underwent a telephone screen before attending the baseline visit. This telephone survey was used to determine preliminary inclusion and exclusion parameters. If eligible, the subject was invited to schedule a baseline examination visit.

Baseline Examination Visit

Upon arrival to the National University of Health Sciences Whole Health Center in Lombard, Illinois, a research assistant briefly described the visit and asked the subject to complete 4 self-administered questionnaires: a visual analog scale to measure current pain; an Oswestry Disability Index to measure current disability; a Swiss Spinal Stenosis Questionnaire (SSS) to measure symptoms of stenosis; and a brief screening questionnaire to collect information on basic demographic, clinical parameters, and inclusion/exclusion parameters. If the subject was not eligible based on his or her responses, the research assistant informed the subject and the subject received a $25 honorarium for their time.

If the subject continued to be eligible, the research assistant administered the institutional review board–approved informed consent, and the subject underwent a low back physical examination, treadmill test, and lumbar magnetic resonance imaging to determine the presence of eligibility criteria. Magnetic resonance imaging, computed tomographic, or myelography scans from another physician were acceptable as long as they were taken within 6 months of the baseline visit. If the subject was not eligible at the end of the baseline visit, he or she received a $25 honorarium. Eligible subjects continued on to the randomization visit.

This was a pilot study chiefly designed to explore the logistics of recruitment and treatment adherence and to gather preliminary estimates of treatment effect sizes to inform the design of a larger study. Therefore, no formal power calculation was performed using a single primary